



US007387792B2

(12) **United States Patent**
Hirsh et al.

(10) **Patent No.:** **US 7,387,792 B2**
(45) **Date of Patent:** ***Jun. 17, 2008**

(54) **PHARMACEUTICAL COMPOSITION FOR COMPRESSED ANNULAR TABLET WITH MOLDED TRITURATE TABLET FOR BOTH INTRAORAL AND ORAL ADMINISTRATION**

(75) Inventors: **Jane C. Hirsh**, Wellesley, MA (US);
Kamal K. Midha, Hamilton (BM);
Mark Hirsh, Wellesley, MA (US);
Whe-Yong Lo, Canton, MA (US)

(73) Assignee: **Collegium Pharmaceutical, Inc.**,
Cumberland, RI (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 119 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **11/041,474**

(22) Filed: **Jan. 24, 2005**

(65) **Prior Publication Data**

US 2005/0123609 A1 Jun. 9, 2005

Related U.S. Application Data

(63) Continuation of application No. 10/015,930, filed on Nov. 30, 2001, now Pat. No. 6,863,901.

(51) **Int. Cl.**

A61K 9/20 (2006.01)

A61K 9/22 (2006.01)

A61K 9/24 (2006.01)

A61K 9/46 (2006.01)

(52) **U.S. Cl.** **424/472**; 424/464; 424/466;
424/468; 424/471; 424/473

(58) **Field of Classification Search** None
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,297,599 A 9/1942 Wilen
3,873,727 A 3/1975 Fusari et al.
3,898,323 A 8/1975 Fennell et al.
4,004,036 A 1/1977 Schmitt
4,139,589 A 2/1979 Beringer et al.
4,229,447 A 10/1980 Porter
4,322,433 A 3/1982 Leslie et al.
4,571,395 A 2/1986 Peck
4,619,934 A 10/1986 Sunshine
4,661,492 A 4/1987 Lewis et al.
4,783,465 A 11/1988 Sunshine
4,814,181 A 3/1989 Jordan et al.
5,053,032 A 10/1991 Barclay et al.
5,064,656 A 11/1991 Gergely et al.
5,082,667 A 1/1992 Van Scoik
5,156,850 A * 10/1992 Wong et al. 424/473
5,248,310 A 9/1993 Barclay et al.
5,294,433 A 3/1994 Singer et al.
5,314,697 A 5/1994 Kwan
5,362,496 A 11/1994 Baker et al.
5,368,588 A 11/1994 Bettinger et al.

5,369,588 A 11/1994 Hayami et al.
5,385,941 A 1/1995 Fawzi
5,407,339 A 4/1995 Fehlhäfer
5,407,686 A 4/1995 Patel et al.
5,451,409 A 9/1995 Rencher et al.
5,512,293 A 4/1996 Landrau et al.
5,512,299 A 4/1996 Place et al.
5,558,879 A 9/1996 Chen et al.
5,573,776 A 11/1996 Harrison et al.
5,595,997 A 1/1997 Aberg
5,609,884 A 3/1997 Desai
5,648,358 A 7/1997 Mitra
5,656,284 A 8/1997 Balkin
5,702,723 A 12/1997 Griffin
5,739,136 A 4/1998 Ellinwood, Jr. et al.
5,756,125 A 5/1998 Desai
5,776,493 A 7/1998 Barclay et al.
5,807,579 A 9/1998 Vilkov
5,827,180 A 10/1998 Goodman
5,827,852 A 10/1998 Russell
5,900,421 A 5/1999 Handley

(Continued)

FOREIGN PATENT DOCUMENTS

EP 0 584 594 3/1994

(Continued)

OTHER PUBLICATIONS

Hackhs, "Chemical Dictionary", 2nd Edition, pp. 185-186, Jun. 30, 1938.

(Continued)

Primary Examiner—S. Tran

(74) *Attorney, Agent, or Firm*—Pabst Patent Group LLP

(57) **ABSTRACT**

New pharmaceutical compositions in unit dosage form are disclosed for both intraoral and oral administration to a patient, said unit dosage form configured to be placed intraorally of said patient, which comprises:

- as a first portion, at least one discrete molded trituate tablet comprising a therapeutically effective amount of at least one pharmaceutically active ingredient capable of intraoral administration; and
- as a second portion located around the said first portion, a therapeutically effective amount of at least one pharmaceutically active ingredient capable of oral administration and which is releasable and orally ingestible by the patient after the molded trituate tablet has disintegrated or has dissolved intraorally.